K021337

JUL 3 2002

ATTACHMENT 5

510(k) Summary

April 15,2002

Contact Information: Aesthetic and Reconstructive Technologies, Inc. (AART)
3545 Airway Drive, Suite 108
Reno, NV 89511
(775) 853-6800 / FAX (775) 853-6805
Winston A. Andrews

Proprietary Name: AART Pectoralis Implant
Common Name: Silicone Elastomer Pectoralis Implant
Classification Name: Implant, Muscle, Pectoralis

Substantial Equivalence: The AART Pectoralis Implant is substantially equivalent in function, design, performance and materials to the Pectoralis Implant marketed by Allied Biomedical Corporation of Ventura, CA and the Seare Biomedical Pectoralis Implant marketed by Seare Biomedical Corp. of Salt Lake City, Utah.

Device Description: The AART Pectoralis Implants are manufactured from a medical grade silicone elastomer that has been molded into various convex oval shapes. They are provided in three styles, each with a right and left mirror image. Dimensions of the implants will range from 14.4 cm to 17.6 cm in length with widths from 10.0 cm to 13.5 cm and projection (height) from 1.6 cm to 3.2 cm. The AART Pectoralis Implants are intended to be used for augmentation of the chest by placing the implant submuscular of the pectoralis muscle. They can also be used to reconstruct the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle). The surface characteristic of the implants is smooth. The AART Pectoralis Implants will be offered non-sterile.

Intended Use: The intended use for the AART Pectoralis Implant is augmentation of the chest to add definition to the pectoralis muscle by placing submuscular. It may also be used for reconstruction of the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle).

Predicate Device: The AART Pectoralis Implant is substantially equivalent in material, design, function, and performance to the Pectoralis Implant marketed by Allied Biomedical Corp. and the Pectoralis Implant marketed by Seare Biomedical Corp. All products have identical intended uses and are offered in similar shapes and sizes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Aesthetic and Reconstructive Technologies, Inc.
c/o Ms. Catherine Riple
5871 Lone Pine Place
Pasorobles, California 93446

Re: K021337
Trade Name: AART Pectoralis Implant
Regulation Name: Prosthesis, Muscle, Pectoralis
Regulatory Class: Unclassified
Product Code: MIC
Dated: April 15, 2002
Received: April 26, 2002

Dear Ms. Riple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638
2041 or (301) 443-6597 or at its Internet address
HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AMENDMENT 1

510(k) NUMBER (IF KNOWN): K021337

DEVICE NAME: AART Pectoralis Implant

INDICATIONS FOR USE:

The intended use for the AART Pectoralis Implant is augmentation of the chest to add definition to the pectoralis muscle by placing submuscular. It may also be used for reconstruction of the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-9

MRO for CMW

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021337